Liza M. Walsh
Selina M. Ellis
Hector D. Ruiz
Christine P. Clark
WALSH PIZZI O'REILLY FALANGA LLP
Three Gateway Center
100 Mulberry Street, 15th Floor
Newark, NJ 07102
(973) 757-1100

Attorneys for Plaintiffs

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

TEVA BRANDED PHARMACEUTICAL PRODUCTS R&D, INC., and NORTON (WATERFORD) LTD.,

Civil Action No. 2:24-cv-00909 (SRC)(MAH)

Plaintiffs,

٧.

CIPLA USA, INC. and CIPLA LTD.,

Defendants.

TEVA BRANDED PHARMACEUTICAL PRODUCTS R&D, INC., and NORTON (WATERFORD) LTD.,

Plaintiffs,

٧.

CIPLA USA, INC. and CIPLA LTD.,

Defendants.

Civil Action No. 2:24-cv-05856 (SRC)(MAH)

STIPULATION AND [PROPOSED] ORDER

Plaintiffs Teva Branded Pharmaceutical Products R&D, Inc. ("Teva") and Norton (Waterford) Ltd. ("Norton") (collectively, "Teva") and Defendants Cipla USA, Inc. and Cipla Ltd. (collectively, "Cipla"), by their undersigned counsel, stipulate and agree as follows:

WHEREAS, after receiving Notice of Paragraph IV Certifications from Cipla, which seeks regulatory approval of Cipla's beclomethasone dipropionate metered aerosol inhalation products, Teva filed a Complaint asserting infringement of U.S. Patent Nos. 8,132,712 (the "'712 patent"), 8,931,476 (the "'476 patent"), 10,022,509 (the "'509 patent"), 10,022,510 (the "'510 patent"), 10,086,156 (the "'156 patent"), 10,561,808 (the "'808 patent"), 10,695,512 (the "'512 patent"), 10,792,447 (the "'447 patent"), 11,395,888 (the "'888 patent"), 11,395,889 (the "'889 patent"), 11,559,637 (the "'637 patent"), and 11,583,643 (the "'643 patent") in Civil Action No. 2:24-cv-00909 (SRC)(MAH) ("the 24-909 Action"), which are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") in connection with Plaintiffs' QVAR RediHaler® (beclomethasone dipropionate, 40 mcg) product pursuant to 21 U.S.C. § 355.

WHEREAS, after receiving additional Notice of Paragraph IV Certifications from Cipla, Teva filed a Complaint asserting infringement of U.S. Patent Nos. 11,793,953 (the "'953 patent"), 11,865,247 (the "'247 patent"), and 11,896,759 (the "'759 patent") in Civil Action No. 2:24-cv-05856 (SRC)(MAH) ("the 24-5856 Action"), which are listed in the Orange Book in connection with Plaintiffs' QVAR RediHaler® (beclomethasone dipropionate, 40 mcg) product pursuant to 21 U.S.C. § 355.

WHEREAS, Teva and Cipla previously stipulated to consolidation of the 24-909 and 24-5856 Actions. *See* C.A. No. 24-909, D.I. 10.

WHEREAS, Cipla's responsive pleadings in the 24-909 and 24-5856 Actions are due on or before June 14, 2024.

WHEREAS, no earlier than June 3, 2024, Teva received a Notice of Paragraph IV Certification from Cipla relating to U.S. Patent No. 11,957,832 (the "'832 patent") in connection with Cipla's efforts to seek regulatory approval of Cipla's beclomethasone dipropionate metered aerosol inhalation products.

NOW THEREFORE, Teva and Cipla hereby stipulate and agree, subject to the approval of the Court, as follows:

- 1. To conserve judicial resources, Teva and Cipla agree to consolidate the 24-909 and 24-5856 Actions with the forthcoming Complaint relating to Cipla's Notices of Paragraph IV Certification in connection with the '832 patent, for all purposes, including discovery, case management, and trial, subject to further order of the Court.
- 2. Teva agrees to file the Complaint relating to the '832 patent on or before June 21, 2024.
- 3. The parties agree that Cipla shall have until July 3, 2024, to file an answer, move or otherwise respond to the above referenced Complaints.

Respectfully submitted,

Dated: June 13, 2024

OF COUNSEL:

David I. Berl

Benjamin M. Greenblum

Elise M. Baumgarten

Kathryn S. Kayali

Ben Picozzi

Ricardo Leyva

Richard Hildreth III

WILLIAMS & CONNOLLY LLP

680 Maine Avenue S.W.

Washington, DC 20024

Tel: (202) 434-5000

dberl@wc.com

bgreenblum@wc.com

ebaumgarten@wc.com

kkayali@wc.com

bpicozzi@wc.com

rleyva@wc.com

rhildreth@wc.com

WALSH PIZZI O'REILLY FALANGA LLP

s/Liza M. Walsh

Liza M. Walsh

Selina M. Ellis

Hector D. Ruiz

Christine P. Clark

WALSH PIZZI O'REILLY FALANGA LLP

100 Mulberry Street, 15th Floor

Newark, New Jersey 07102

Tel: (973) 757-1100

lwalsh@walsh.law

sellis@walsh.law

hruiz@walsh.law

cclark@walsh.law

Attorneys for Plaintiffs Teva Branded

Pharmaceutical Products R&D, Inc. and Norton

(Waterford) Ltd.

Attorneys for Plaintiffs Teva Branded Pharmaceutical Products R&D, Inc. and Norton (Waterford) Ltd.

K&L GATES LLP

s/Loly G. Tor

Loly G. Tor (loly.tor@klgates.com)

K&L GATES LLP

One Newark Center, 10th Floor Newark, NJ 07102

3/102

(T) 973.848.4026

(F) 973.848.4001

Attorneys for Defendants Cipla USA, Inc. and Cipla Ltd.

SO ORDERED

s/Michael A. Hammer

Michael A. Hammer, U.S.M.J.

Date: 6/13/2024